(f) *Previously approved programs.* A Commission-approved quality assurance program that satisfies the applicable criteria of Appendix B of Part 50 of this chapter, and that is established, maintained, and executed with regard to transport packages, will be accepted as satisfying the requirements of paragraph (b) of this section. Before first use, the licensee shall notify the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, of its intent to apply its previously approved Appendix B program to transportation activities. The licensee shall identify the program by date of submittal to the Commission, Docket Number, and date of Commission approval.

(g) *Radiography containers.* A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of §34.31(b) or equivalent Agreement State requirement, is deemed to satisfy the requirements of §71.12(b) and 71.101(b) of this chapter.

[60 FR 50264, Sept. 28, 1995, as amended at 62 FR 28973, May 28, 1997]

§71.103 Quality assurance organization.

(a) The licensee[3] shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. The licensee shall clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(b) The quality assurance functions are—

(1) Assuring that an appropriate quality assurance program is established and effectively executed; and

(2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the safety-related functions have been performed correctly.

(c) The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to—

(1) Identify quality problems;

(2) Initiate, recommend, or provide solutions; and

(3) Verify implementation of solutions.

(d) The persons and organizations performing quality assurance functions shall report to a management level that assures that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided.

(e) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom.

(f) Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.

§71.105 Quality assurance program.

(a) The licensee shall establish, at the earliest practicable time consistent with the schedule for accomplishing

[3] While the term ''licensee'' is used in these criteria, the requirements are applicable to whatever design, fabrication, assembly, and testing of the package is accomplished with respect to a package prior to the time a package approval is issued.

the activities, a quality assurance program that complies with the requirements of §§ 71.101 through 71.137. The licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(b) The licensee, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

(c) The licensee shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

(1) The impact of malfunction or failure of the item to safety;

(2) The design and fabrication complexity or uniqueness of the item;

(3) The need for special controls and surveillance over processes and equipment;

(4) The degree to which functional compliance can be demonstrated by inspection or test; and

(5) The quality history and degree of standardization of the item.

(d) The licensee shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program which they are executing.

§ 71.107 Package design control.

(a) The licensee shall establish measures to assure that applicable regulatory requirements and the package design, as specified in the license for those materials and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the materials, parts, and components of the packaging.

(b) The licensee shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures, among participating design organizations, for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design, by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in